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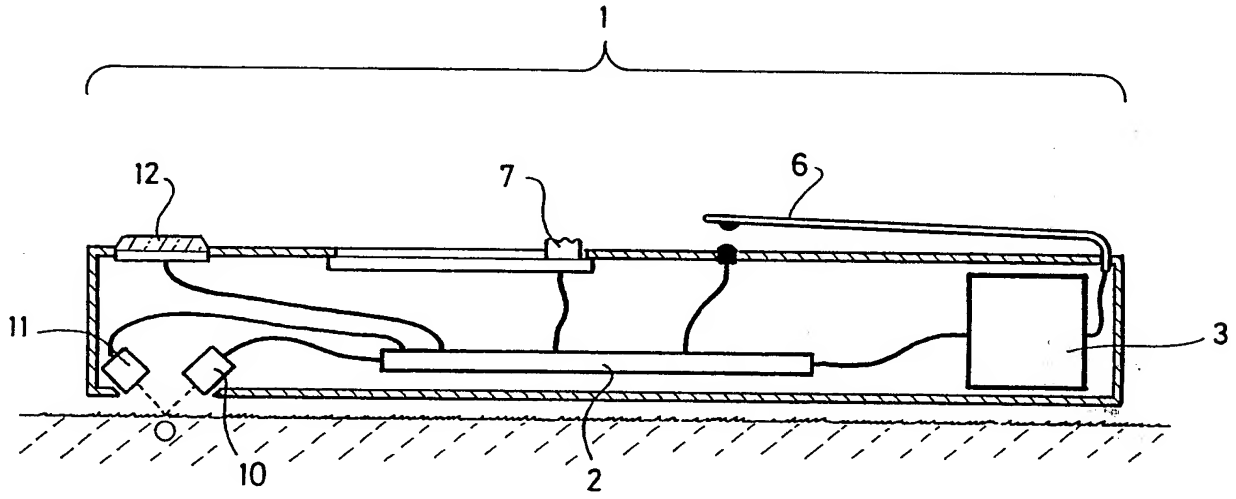

(57) Abstract

The present invention relates to a haematology device for use in detecting blood within the skin of a mammal, notably a human being, which device comprises: a) a hand portable housing (1) adapted to be passed over the skin of the mammal; b) an infra-red signal emitter (10) operatively associated with the housing (1) and adapted to project a near infra-red signal having a wavelength of from 700 to 2,500 nanometres onto the skin of the mammal; c) a sensor (11) in operative association with the emitter (10) and adapted to detect the near infra-red signal re-radiated from the skin of the mammal; d) comparator means for comparing the signal emitted with the signal detected by the sensor to monitor the proportion of the emitted signal which is absorbed and/or scattered by the skin of the mammal; and e) means (12) to emit a signal to indicate when the proportion of the emitted signal which is absorbed and/or scattered is above or below a predetermined level. The invention also provides methods for monitoring blood analytes by using a non-invasive pathological device in association with the device of the invention; and a method for locating abnormalities in the skin using the device of the invention.

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TITLE: HAEMATOLOGY DEVICE

The present invention relates to an haematology device and methods for using it, notably to a device and method for locating blood vessels within a human body, particularly in association with a non-invasive spectroscopic device for establishing the amount of glucose or other materials in the blood within the located vessel and/or within the capillary matrix/extra-cellular fluid bed.

BACKGROUND TO THE INVENTION:

During the medical treatment of patients, it is usually desirable to obtain pathological information about the state of the patient's body so as to monitor the management of the patient's treatment. Typically, much of this information is obtained from blood samples drawn from the patient. Where medication is given or in acute cases, it may be necessary to monitor the blood on a frequent basis, since the blood will reflect changes, often dramatically and within minutes, in the patient's state.

Hitherto, the conventional method for taking blood samples has been to insert the needle of a syringe into a blood vessel, for example a vein, and to draw off a sample of blood from the vessel. However, in many patients, notably the young, the elderly or the infirm, the exact location of a suitable vein may be difficult to detect. Whilst the surface veins in some areas of the body are visible and veins can in some cases be made more prominent by the application of a tourniquet or inflatable cuff, the vein may still be difficult to locate accurately. As a result, the nurse or physician may make a number of attempts to insert the needle into the vein, which is objectionable. Furthermore, where blood is drawn in this manner, some bruising of the patient's skin may occur. This bruising

will be more pronounced and painful when samples have to be drawn frequently.

In order to reduce the problems caused by drawing blood samples from a patient, it has been proposed to use non-invasive pathology techniques to monitor the content of glucose, cholesterol or other chemicals in the blood or the extra-cellular fluid through the skin without the need to draw a sample of blood or fluid from the patient. Such techniques use pulsed or modulated light sources to illuminate and excite molecules of a material to emit an acoustic shock wave due to the light absorbed by that material. The amount of light absorbed and the frequency of the acoustic signal emitted are characteristic of the material. The spectoscopic devices used in such non-invasive techniques include optoacoustic devices where the light source is pulsed and photacoustic devices where the light source is modulated. For convenience, the term optoacoustic spectroscopic techniques and devices will be used herein to denote both types of technique and device.

However, such non-invasive techniques can not be consistently performed to give accurate and reliable results if the device is not accurately located over the blood vessel or the desired area of the capillary matrix/extra-cellular fluid bed in the skin. This is particularly the case when an operator attempts to use the technique to monitor the level of cholesterol or other large molecules in the blood. Such molecules do not diffuse into the tissue around the vein at a rate or in an amount sufficient for observation of that tissue to give an accurate representation of the level of those materials in the blood stream. It is therefore essential that the device be located precisely over the vein so that the levels in the blood stream as opposed to the capillaries and/or the extra-cellular fluid are monitored.

At present the proposed non-invasive devices have to be located visually over the vein or other blood vessel, which results in errors of placement of the device. Non-invasive techniques have therefore to be considered unsuitable for monitoring many of the chemicals in the blood which it would be desirable to monitor.

A further problem with the use of non-invasive techniques is that they will give misleading results if they are carried out on an area of the skin where the proportion of the capillary matrix to the extra-cellular fluid is distorted, for example where there is a scar or callous on the skin or a mole, birthmark or other abnormal pigmentation of the skin. Whilst such areas may in some cases be identified visually by the patient, the abnormality often can not be seen by the naked eye. Furthermore, those suffering from diabetes or other ailments often have impaired eyesight and cannot detect when they are trying to take a reading in such an abnormal skin area.

I have found that near infra-red radiation is absorbed or scattered to a greater extent by blood in the skin of a mammal, for example in a vein, capillary or other blood vessel (for convenience hereinafter denoted generically by the general term blood vessel) within the skin, than elsewhere on the skin. The change in level of such radiation re-radiated from the skin thus provides a simple and effective method for locating a blood vessel underlying the skin of the mammal.

This discovery enables the location of a blood vessel to be established simply and effectively without applying cuffs or tourniquets or otherwise invading the body of the patient, so that a nurse or phsysician can draw blood

samples with virtually no risk of unnecessary bruising due to abortive attempts to locate the blood vessel with the needle of a syringe.

The discovery also enables a non-invasive pathology device to be located consistently and accurately above a blood vessel. This enables a non-invasive technique to be used in circumstances where it might not otherwise have been suitable and to monitor chemicals within the blood vessel for which such monitoring techniques have not hitherto be considered suitable.

I have also found that the discovery can be used to discriminate between dermis which has a normal ratio of capillary matrix to extra-cellular fluid and dermis where this ratio is distorted. Users with impaired eyesight can thus ensure that they are not attempting to use a non-invasive pathology device in an area of skin which could give rise to mis-leading results.

The distortion also occurs where the cellular structure of the skin is abnormal, for example cancerous or pre-cancerous conditions, since this will affect the proportion of the capillary matrix to the extra-cellular fluid in the skin at this point. The discovery thus enables a user to carry out a simple scan of the body of a patient to locate many such abnormalities which might not be visible to the user.

SUMMARY OF THE INVENTION:

Accordingly, the present invention provides a device for detecting the presence of blood, notably in a blood vessel, below the surface of the skin of a mammal, which device comprises:

a. a hand portable housing adapted to be passed over the

skin of the mammal;

b. an infra-red signal emitter operatively associated with the housing and adapted to project a near infra-red signal having a wave length of from 700 to 2500 nanometres onto the skin of the mammal;

c. a sensor in operative association with the emitter and adapted to detect the near infra-red signal re-radiated from the skin of the mammal;

d. comparator means for comparing the signal emitted with the signal detected by the sensor to monitor the proportion of the emitted signal which is absorbed and/or scattered by the skin of the mammal; and

e. means to emit a signal to indicate when the proportion of the emitted signal which is absorbed and/or scattered is above or below a predetermined level, and preferably to actuate a display means.

The invention also provides a method for locating blood, notably in a blood vessel, below the surface of the skin of a mammal, which method comprises passing a device of the invention over the skin of the mammal and detecting an area where the proportion of the emitted signal which has been absorbed and/or scattered by the skin of the mammal lies above or below a predetermined level, which area corresponds to the location of a blood vessel and/or to a variation in the level of capillary matrix within the skin of the mammal.

The signal from the emitter may be both absorbed and scattered by the blood within the skin, for example by the blood flowing through a blood vessel, so that only part of the signal re-radiated from the blood is directed at the sensor. Furthermore, part of the emitted signal from the emitter may be reflected at the surface of the skin being illuminated by the emitter. For convenience the term re-radiated signal will be used herein to denote both the

signal reflected from the skin and the reduced signal re-radiated from the blood.

As indicated above, the method and device of the invention are of especial use in association with a non-invasive pathologic, eg. optoacoustic spectroscopic, method for monitoring components of the blood within the blood vessel and/or in the capillary matrix/extra-cellular fluid bed, in which case the device and method of the invention are used to locate the blood vessel accurately to enable the non-invasive device to be focussed accurately upon the blood vessel. Alternatively, the device and method of the invention can be used to detect changes in the capillary matrix/extra-cellular fluid bed in the skin to detect abnormalities in the skin. In each case the device and method monitors the level of the re-radiated signal versus the emitted signal to detect changes in their relative proportions due to the presence of a blood vessel in the skin.

The invention can be applied to the location of subcutaneous blood vessels in a wide range of mammals, for example in horses. However, the invention is of especial use in the detection of surface veins or capillary matrixes in human beings at a depth of from 40 micrometres to several centimetres below the surface of the skin, ie. within or just below the dermis of the person. For convenience the invention will be described in terms of the application of the invention to humans.

The housing for the device of the invention can take a number of forms, but is typically a generally cylindrical housing containing the near infra-red emitter and sensor and the necessary electronic circuitry for the comparitor and display circuits. For convenience, the invention will be described hereinafter in terms of a generally

cylindrical housing, although it will be appreciated that, within reason, any other shape of housing may be used.

The housing contains the near infra-red emitter and the sensor. These are of any suitable type which emit and detect radiation with wave lengths in the range 700 to 2500, preferably 800 to 2000, notably 800 to 1300, nanometres, since I have found that this is the radiation which is preferentially absorbed by the blood vessels. The emitter typically takes the form of an infra-red emitting diode or laser diode. However, where it is desired to detect blood vessels at depths greater than 150 micrometres, a semiconductor laser or laser diode operating at the desired frequency band may be required. Typically, the emitter will have a power output of from 1 to 50 milliwatts where the device is to locate blood vessels within 2000 micrometres of the skin surface. Where the device is to detect blood or features at greater depths, the emitter can have a power of up to 5 watts, and exceptionally 10 to 40 watts if operating at a wavelength of substantially 900 nanometres. It will be appreciated that for powers in excess about 50 milliwatts, it will be desirable to pulse the emitter to reduce localised heating of the skin. Typically, the emitter will be pulsed with from 50 to 1,500 nanosecond on periods and preferably with similar or greater off periods, ie. at a 50% or lower duty cycle. This can be achieved using conventional control circuitry. The optimum power and pulse cycle for the emitter can readily be determined for each given use.

If desired, filters or the like can be used in conjunction with the signal source to reduce the wave length spread of the emitted signal. The use of a mono- or near mono-chromatic signal emitter enables the device of the invention to monitor specific materials in the skin.

The signal from the emitter can be collimated or focussed upon the area of the skin to be observed using conventional techniques. Suitable diodes incorporating focussing mirrors or a lens are commercially available or can readily be assembled from commercially available components using known techniques.

The emitter will typically be located immediately adjacent or projecting from that face of the device which is to be passed over the skin of the person in contact with or in close proximity to the skin. If desired, the emitter can be mounted behind a protective quartz, glass, plastic or similar wall which is transparent to the near infra-red signal and which is to be moved in contact with the skin of the person. Alternatively, the emitter can be encased in a suitable resin to provide a bead which can be used in direct contact with the skin. However, it is within the scope of the present invention to locate the emitter device, for example an NdYAG or other laser at a remote location and to transmit the emitted signal to the hand held housing by an optic fibre or other suitable means. For convenience the term emitter is used herein to denote the radiating element, for example the diode or the end of the optic fibre, from which the emitted signal is discharged onto the skin to be observed, and not solely the mechanism at which the signal originates.

The emitter will usually be mounted so that it directs its radiation substantially normally onto the surface of the skin of the person. However, the emitter can be mounted to direct its radiation at an angle, for example at $\pm$ 45° to the normal, onto the skin of the person, so that the return signal from the skin is re-radiated directly onto the sensor carried in the housing.

The sensor can be of any suitable type, having regard to

the type of emitter used, for example a charge couple device or a phototransistor. If desired the sensor can incorporate a lens and/or a filter means for reducing the effect of extraneous radiation. Thus, it will usually be preferred for the sensor to be located in a skirt, shroud or other secondary housing within the main housing to reduce the amount of scattered light or infra-red radiation falling on it which has not emanated from the emitter. The sensor may also be provided with filters to limit the wave length spread of the signal which is accepted at the sensor to enhance the wavelength specificity of the device. Alternatively, such wave length filtering may be carried out in the processing of the signal from the sensor. It is preferred that the sensor be located as close as practicable to the emitter and the skin to be observed to reduce the risk of extraneous light falling upon it.

In a particularly preferred configuration, the emitter and sensor are located adjacent the end of one side wall of an elongated housing so that the emitter directs its radiation onto the skin of the person at an angle of from 10° to 45° to normal to the plane of the skin, and the sensor is located on the return path of the re-radiated return signal from the skin. If desired the return signal can be passed through a lens or aperture to assist in the focussing of the re-radiated signal on the sensor or to reduce the amount of extraneous light falling on the sensor.

The device also includes means for comparing the proportion of the emitted radiation which is re-radiated from the illuminated area of the skin and detected by the sensor. Such means can be of conventional signal comparitor design and construction. If necessary, the circuitry can incorporate one or more amplifier circuits to enhance the re-radiated signal for comparison purposes, and can include electronic filter or other means to discriminate between

components of the signal observed by the sensor. Such means can be pre-set or can be manually adjustable to vary the selectivity of the device.

The comparitor can be pre-set so that it will emit a signal to actuate a display or alarm device when the proportion of the emitted signal being observed at the sensor falls below a predetermined value, corresponding to the presence of a blood vessel in the skin being scanned. Alternatively, the comparitor circuit can be set to actuate the display or alarm when the predetermined level is exceeded, as when the device passes over an area where the proportion of the capillary bed matrix in the dermis falls below a level corresponding to a normal area of the skin. However, it is preferred that the circuit incorporate a sensitivity control for varying the proportion of the emitted to observed signal required to actuate the alarm and/or display device. In this way, the device of the invention can be set to detect large blood vessels or vessels close to the skin surface, but to ignore small vessels or deep vessels and to reflect different skin characteristics of the person being scanned. In a preferred embodiment, the circuit incorporates a potentiometer for varying the sensitivity, and the setting of the potentiometer is controlled by a manually selectable slider or knob accessible to a user of the device or by means of a micro-processor control to provide a ten to one hundred fold variation in the signal strength required to actuate the display or alarm.

Where the device is used to detect a blood vessel, the signal from the comparator circuit actuates a display or alarm device, which is preferably a visual one, for example a pointer on a dial or a light which illuminates or extinguishes. Alternatively, the display can be an audio signal, for example a buzz or a tone. The display or alarm

device can be of conventional design and construction. In other applications of the device of the invention, indicated above, the signal from the comparator circuit can actuate operation of some other process, device or mechanism. For example, by suitable processing of the re-radiated signal, an operator may be able to discriminate between levels of material in the skin matrix so as to identify possible cancerous or pre-cancerous conditions. Alternatively, since the device of the invention responds to the presence of blood in the skin being observed, it is possibe to calculate the ratio of blood to extra-cellular fluid in the skin being observed. This ratio can be applied as a correction factor to a non-invasive device monitoring an analyte within the capillary matrix/extra-cellular fluid bed above a blood vessel and close to the skin surface so as to compensate for changes in that ratio, for example to aloow the non-invasive device to be operated as a blood exclusive or extra-cellular fluid exclusive device.

The device conveniently incorporates a power source, for example a battery or re-chargeable cell, so that the device is self contained and operates off a low voltage for safety purposes. It is also desired that the device incorporate a power on/off switch, which can be of the conventional mechanical type or a touch type switch, for example one operating on a capacitance basis.

As indicated above, the device of the invention finds especial use in association with a non-invasive pathological device for monitoring the composition of the blood in the located blood vessel or in the capillary matrix/extra-cellular fluid bed through the skin so as to avoid the need to draw a blood sample. The non-invasive device can use a wide range of techniques, for example tuned Raman spectroscopy, broadband light reflectance,

laser transmission or optoacoustic methods, to monitor a wide range of blood components. The device will typically monitor the glucose, urea or cholesterol levels in the blood or, in some cases, in the capillary matrix/extra-cellular fluid bed using an optoacoustic spectroscopic method. Typical of such devices is that described in my co-pending European Patent Application No 0 282 234, the subject matter of which is incorporated herein by reference. For convenience, the present invention will be described hereinafter in terms of such a device.

The device of the invention can be used to locate the required point on the skin, for example a blood vessel, so that the location can be accurately marked, for example by a pen, on the surface of the skin. A separate non-invasive device can subsequently be used at the marked location to monitor the desired component of the blood flowing through the vein or other blood vessel located at that position and/or in the capillary matrix/extra-cellular fluid bed associated with the located blood vessel. It will be appreciated that some blood components, for example cholesterol, do not diffuse into the capillary matrix/extra-cellular fluid bed sufficiently to provide a clinically useful means for establishing their content in the blood, and that the monitoring of those components is best done on the blood within a located vein. Alternatively, as indicated above, the re-radiated signal can be processed to enable the non-invasive device to monitor analytes which are in the capillary matrix/extra-cellualr fluid bed and to compensate for variations in the capillary matrix level.

Alternatively, the non-invasive device can be incorporated into the device of the invention so that a single housing contains the necessary mechanisms and circuitry to perform both the location and monitoring operations. In this case

it may be desirable to provide the comparator circuit of the location portion of the device with means for detecting when the proportion of the observed to the emitted near infra-red signal observed by the sensor passes through a minimum, thus indicating when the device is closest to the blood vessel, and with means to provide a signal at this point to actuate the blood composition monitoring means. This latter may be done manually when the operator observes the passage through the minimum position, or can be achieved by suitable electronic interlinking of the location and monitoring portions of the device.

It is preferred that the comparator circuit incorporate a memory, for example a look up or read only memory in a suitable micro-processor, which can retain examples of the proportions of emitted to observed signal patterns against which the actual signals can be compared in order to determine when the device is located accurately over a vein and to determine the centre line of that vein for the purposes of positioning or actuating the non-invasive pathological device or when the device is located over an area of skin having an abnormal capillar matrix/extra-cellular fluid ratio.

The micro-processor can also be used to compensate for ambient illumination, for example by operating the emitter on a pulsed basis and monitoring the background illumination observed between the pulses by the sensor so that those levels can be discounted in comparing the emitted and observed signals for an adjacent pulse. Furthermore, the micro-processor can detect abnormal conditions, for example excessive ambient illumination due to incorrect placing of the device against the skin allowing excessive light to play upon the sensor. This can be used to alert the user of the device so that the user corrects those abnormal conditions, if possible, or

discontinues use of the device until the conditions are rectified; or this can be used as part of a safety cut-off mechanism to reduce the risk of accidental damage to the user where the device is actuated when not directed at the skin.

In a further alternative, the device of the invention can be operated in conjunction with a mid infra-red ablative device which is used to cauterise the skin to penetrate the stratum corneum and expose blood infused capillary matrix/extra-cellular bed. This would then be available for analysis, for example by a non-invasive pathological device as described above. The proportion of the emitted near infra-red radiation observed by the sensor of the device of the invention will reduce as the hole in the skin formed by the ablative device deepens and this can be used to accurately control the ablative process to minimise scarring and pain. In such an application, the emitter and sensor of the device of the invention can be located adjacent an optic fibre or the like which is used to direct the mid infra-red cauterising beam onto the skin of the person.

The device of the invention can be made from any suitable electronic components and materials using conventional electronic design and manufacturing techniques.

DESCRIPTION OF THE DRAWINGS:

The invention will now be illustrated with reference to a preferred embodiment thereof as shown in the accompanying drawings in which Figure 1 is a diagrammatic longitudinal cross-section through the device; Figure 2 is a diagrammatic circuit diagram for the device of Figure 1; and Figure 3 is a diagrammatic representation of an alternative circuit for use in the device of Figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT:

The device comprises a cylindrical pen shaped housing 1 containing a circuit board 2 carrying the control and adjustment circuits described in more detail below. The housing has a battery compartment 3 at one end thereof housing conventional high power batteries as used in a calculator or the like. In the present case, the batteries deliver 5 volts.

The housing carries a clip type or other pressure actuated power on/off switch 6 and a slider 7 for adjusting the value of a potentiometer controlling the sensitivity of the comparitor circuit. The potentiometer preferably provides a broad range of sensitivity settings for the device.

At one end of the housing is located an infra-red emitting diode 10 directing its radiation at an angle of 45° to the axis of the housing, and projecting through an aperture or window in the wall of the housing so that it can be brought into contact with the skin to be observed. The diode emits radiation in the very near infra-red region, for example at wave lengths of from 900 to 1100 nanometres. Reflected radiation is detected by a phototransistor 11 located so as to lie substantially on the centre line of a notional beam of radiation emitted from the emitter 10 and reflected from a surface generally parallel to the axis of the housing and located immediately adjacent the wall of the housing.

The output from the sensor 11 is fed to the comparator circuit on the circuit board 2 to switch on or off a light emitting diode 12 or the like when the proportion of re-radiated signal observed at the phototransistor 11 to the emitted signal falls below the desired level.

The circuit board 2 carries a power on/off switch circuit which delivers a voltage V to the comparitor and adjustment circuits shown diagrammatically in Figure 2. The sensitivity of the device is varied by adjusting the resistance in potentiometer 13 so that the device can be set to detect a vein or capillary matrix/extra-cellular fluid bed at the desired depth or of a certain minimum size. It will be appreciated that the device of the invention can use an active comparitor circuit in which the intensity of radiation from the emitter and that detected by the sensor are both monitored and the proportion of the re-radiated signal to the emitted signal is calculated at pre-set intervals or for each pulse of the emitter. However, it is usually preferred that the emitter emit a substantially fixed level of radiation and that the comparison be carried out assuming that this remains constant. The level of intensity of the re-radiated signal detected at the phototransistor 11 will thus give a direct measure of the proportion of the re-radiated to emitted signal. In this case the sensitivity control merely sets the level of the observed re-radiated signal required to actuate the display device.

In use, the device is adjusted by the user so that the diode 12 illuminates at the lowest sensitivity setting when located above a vein comparable to one in the area where a blood sample should be drawn or comparable to a normal skin capillary matrix to extra-cellular fluid ratio where a non-invasive pathological analytical device would give an accurate result. The adjustment can be set so that the threshold level corresponds to the presence of a large blood vessel, and thus excludes the effect of capillary blood or small blood vessels and of body tissues. As indicated above, the comparator circuit can incorporate a memory which holds pre-set values for signals corresponding to certain types and/or sizes of blood vessel, in which

case the user merely selects the type from the memory, eg. by a dial or numeric pad input, against which the comparator circuit is to compare the observed signal.

The device is then drawn across the skin to be observed, preferably with the emitter 10 and diode 11 in close contact with the skin to reduce the amount of stray illumination falling on the diode 11. The display diode 12 will illuminate whenever the emitter is located over a sufficiently large blood vessel for the proportion of re-radiated signal to emitted signal to fall below the threshold value set by the sensitivity control. Alternatively, the diode 12 will cease to illuminate when the device passes over an area of skin, for example a callous, where the number of capillaries in the dermis falls below a level at which reliable results for the blood analytes could be achieved.

Initially, the device can be set at a high sensitivity to locate blood vessels of a minimum size suitable for drawing blood from. Once the general position of a blood vessel has been located, the precise location can be determined by reducing the sensitivity until the diode 12 is actuated in only a very limited area. The lower the sensitivity setting, the smaller the area over which the diode will actuate so that a user can progressively home in to the centre line of the blood vessel. In this way the device can be used to mark the position at which a non-invasive pathological device can be used to monitor one or more components of the blood within the blood vessel and not within the capillary matrix/extra-cellular fluid bed closer to the surface of the skin.

The device can also be used to follow a blood vessel to detect constrictions or blockages within the vessel which will be detected as interruptions in the actuation of the

diode 12, for example blood clots in varicose veins or, in the case where a laser or laser diode is used as the emitter, blocked cardiac arteries and deep hemorrhaging.

Where the device is to be used in conjunction with a non-invasive spectographic or optoacoustic device, it will be preferred to modify the circuit for the device shown in Figure 1 to incorporate the features shown diagrammatically in Figure 3.

As with the device of Figure 1, the device comprises an infra-red emitter 21 and an infra-red detector 22 which detects infra-red radiation returning from the skin and underlaying tissue. The detector 22 will usually produce an anlalog signal output which is converted to a digital signal in a conventional analog to digital converter 23. The voltage or other analog signal output produced by the detector 22 is preferably buffered in a conventional buffer circuit 24 in order to reduce interaction between the input impedance of the analog to digital converter 23 and the output of the phototransistor 22.

The output of the analog to digital converter 23 is read onto an input port of a microprocessor 25 where the information in the signal is compared to data baselines stored within a memory associated with the microprocessor 25. This process is achieved by the program which resides in the microprocessor. These data baselines can be, for example, stored results from pre-cancerous skin tissue, data from stages of ablation of the skin, data from abnormal or/and normal skin conditions, data from trials with interfering background near infra-red light sources, and so on, to provide a library of data for conditions which may be encountered during use of the device and which are required to be recognised so as to trigger the display device. Thus, by comparing the incoming data from the

analog to digital converter 23 with the range of data stored in the memory, the device can identify which skin condition is being observed by the sensor 22. This can then be displayed as an output on a suitable display (not shown). Alternatively, the microprocessor can be selectively programmed to actuate the display when a specified condition is observed and the device can incorporate switching means or the like whereby a user can select the data baseline in the memory on which the device is to operate and hence the condition the user is seeking to detect.

To optimize the reaction of the device to a wide range of conditions, for example where the device is to be used on a dark skinned as opposed to a light skinned person, the microprocessor can be programmed to adjust the emitter output signal and/or the sensitivity of the sensor in accordance with values held within the memory which are accessed upon input of the expected operating conditions by an operator. This is preferably done via a digital to analog converter 26, which controls the light intensity output by the infra-red emitter 21 and/or the sensitivity of the infra-red detector 22.

Where the haematology device shown in Figure 3 is integrally part of another unit, the output signals from the microprocessor 25 may be used as the input signals to actuate operation of that other device or vice versa, for example to measure the deepening and widening effect of a mid infra-red ablating device. In this case, the memory of the device of Figure 2 would be programmed to recognise the variation of the emitted and re-radiated signals observed by the sensor 22 which corresponds to a given depth and width of ablated tissue. When the desired depth (ie reflectance response) is reached, the display can be actuated to alert the user to begin monitoring the desired

blood analyte. This can be done manually or the device can be interfaced with a suitable optoacoustic device which automatically initiates the blood monitoring cycle.

In another example, the memory and program of the device would have stored the signal characteristics of skin suitable for the performance of optoacoustic spectroscopic analyses of the layer of blood capillaries/extra-cellular fluid located approximately 100 or more micrometres below the skin surface. In this case the program would be set to alert the user to the fact that the region under test was suitable. Alternatively, the program could be set to alert the user when an area not meeting the required suitability criteria due to a reduced level of capillaries in the tissue being observed, so that the user would seek an alternative site for carrying out the analysis.

CLAIMS:

1. A haematology device for detecting the presence of blood below the surface of the skin of a mammal, which device comprises:

a. a hand portable housing adapted to be passed over the skin of the mammal;

b. an infra-red signal emitter operatively associated with the housing and adapted to project a near infra-red signal having a wave length of from 700 to 2500 nanometres onto the skin of the mammal;

c. a sensor in operative association with the emitter and adapted to detect the near infra-red signal re-radiated from the skin of the mammal;

d. comparator means for comparing the signal emitted with the signal detected by the sensor to monitor the proportion of the emitted signal which is absorbed and/or scattered by the skin of the mammal; and

e. means to emit a signal to indicate when the proportion of the emitted signal which is absorbed and/or scattered is above or below a predetermined level.

2. A device as claimed in claim 1 wherein the emitter is a laser, a laser diode or an infra-red emitting diode.

3. A device as claimed in either of claims 1 or 2 wherein the emitter operates at a wavelength in the range 800 to 1300 nanometres.

4. A device as claimed in any one of the preceding claims wherein the emitter has a power of from 1 milliwatt to 5 watts peak power.

5. A device as claimed in claim 4 wherein the device incorporates means for pulsing the emitter with a cycle on time of from 50 to 1,500 nanoseconds.

6. A device as claimed in any one of the preceding claims wherein the emitter is orientated so as to direct its signal at ± 45° to a plane generally parallel to the longitudinal axis of the housing.

7. A device as claimed in any one of the preceding claims wherein the sensor is a charge couple device or a phototransistor.

8. A device as claimed in any one of the preceding claims wherein the sensor is mounted within a secondary housing which is adapted to reduce the amount of scattered or extraneous light not emanating from the emitter which falls upon the sensor.

9. A device as claimed in any one of the preceding claims incorporating means whereby the signal emitted by the emitter and/or the signal detected by the sensor are substantially mono-chromatic signals.

10. A device as claimed in any one of the preceding claims wherein the comparator means incorporates means for varying the predetermined level at which the alarm or display means is actuated.

11. A device as claimed in any one of the preceding claims wherein the comparator means is provided with a memory means containing data relating to a plurality of the signals from the sensor corresponding to conditions which it is expected the device will observe, and the comparator is programmed to compare the signal from the sensor with those in the memory to identify the condition of the skin being observed.

12. A device as claimed in claim 1 substantially as

hereinbefore described.

13. A device substantially hereinbefore described with respect and as shown in any one of the accompanying drawings.

14. A haematology device as claimed in any one of the preceding claims in operative association with a non-invasive spectroscopic device for monitoring a component of blood.

15. A device as claimed in claim 14 wherein the non-invasive device is an optoacoustic spectroscopic device which is housed within the said housing and whose operation is interlinked with the haematology device whereby the signal from the haematology device indicating when the predetermined level has been attained actuates the non-invasive device.

16. A method for locating blood below the surface of the skin of a mammal which comprises passing a device as claimed in any one of the preceding claims over the skin of the mammal and detecting an area where the proportion of the emitted signal which has been absorbed and/or scattered by the skin of the mammal lies above or below a predetermined level, which area corresponds to the location of a blood vessel and/or to a variation in the level of the capillary matrix within the skin of the mammal.

17. A method as claimed in claim 16 wherein the mammal is a human being and the blood to be located is in a vein, capillary or other blood vessel at 40 micrometres or more below the surface of the skin.

18. A method as claimed in either of claims 16 and 17 wherein the haematology device is operatively associated

with a non-invasive optoacoustic spectroscopic device whereby the spectroscopic device can be accurately located over a blood vessel located by the haematology device.

19. A method as claimed in either of claims 16 and 17 wherein the haematology device is operatively associated with a mid infra-red ablative device and the haematology device monitors the operation of the ablative device.

20. A method as claimed in either of claims 16 and 17 wherein the haematology device is used to detect variations in the capillary matrix/extra-cellular fluid ratio in the skin so as to locate abnormalities in the skin.

21. A method as claimed in claim 20 wherein the abnormality is a cancerous or pre-cancerous condition.

22. A method for using a device as claimed in claim 1 substantially as hereinbefore described.

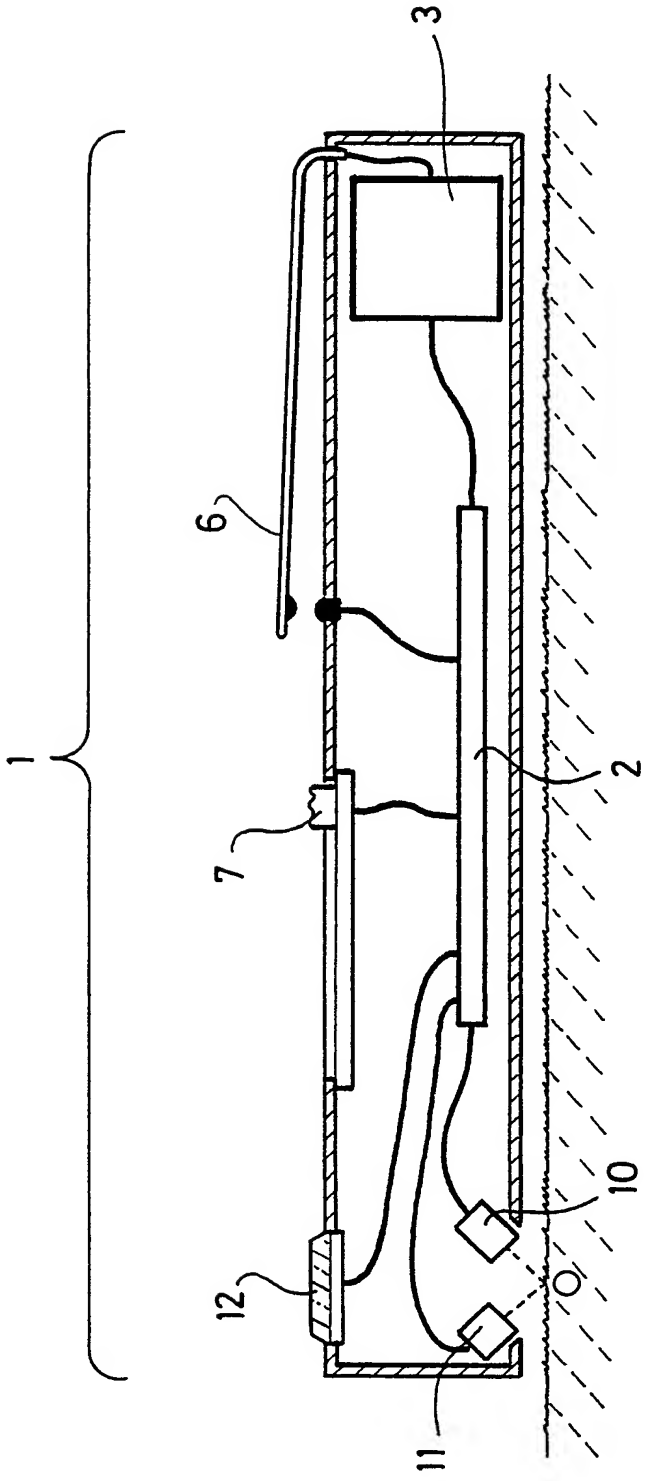

Fig. 1

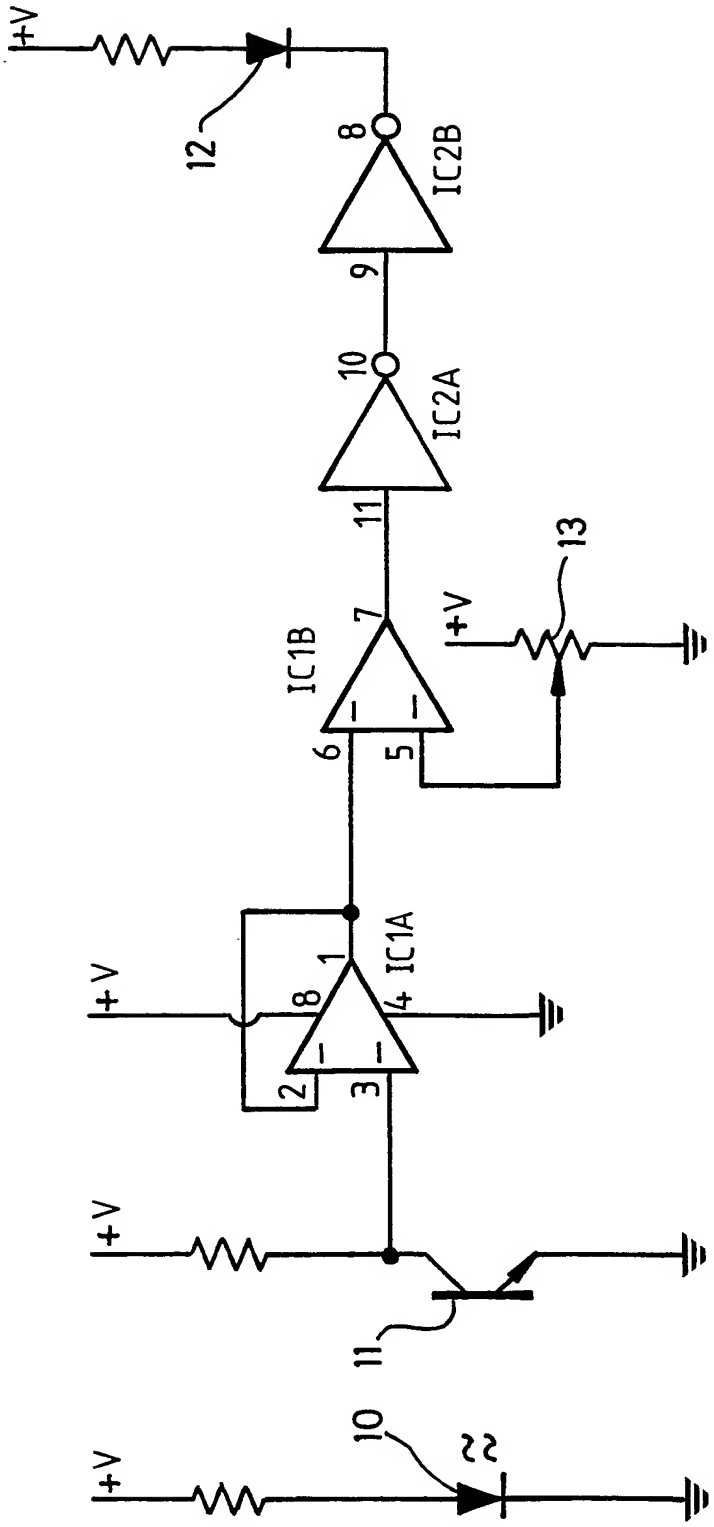

Fig. 2

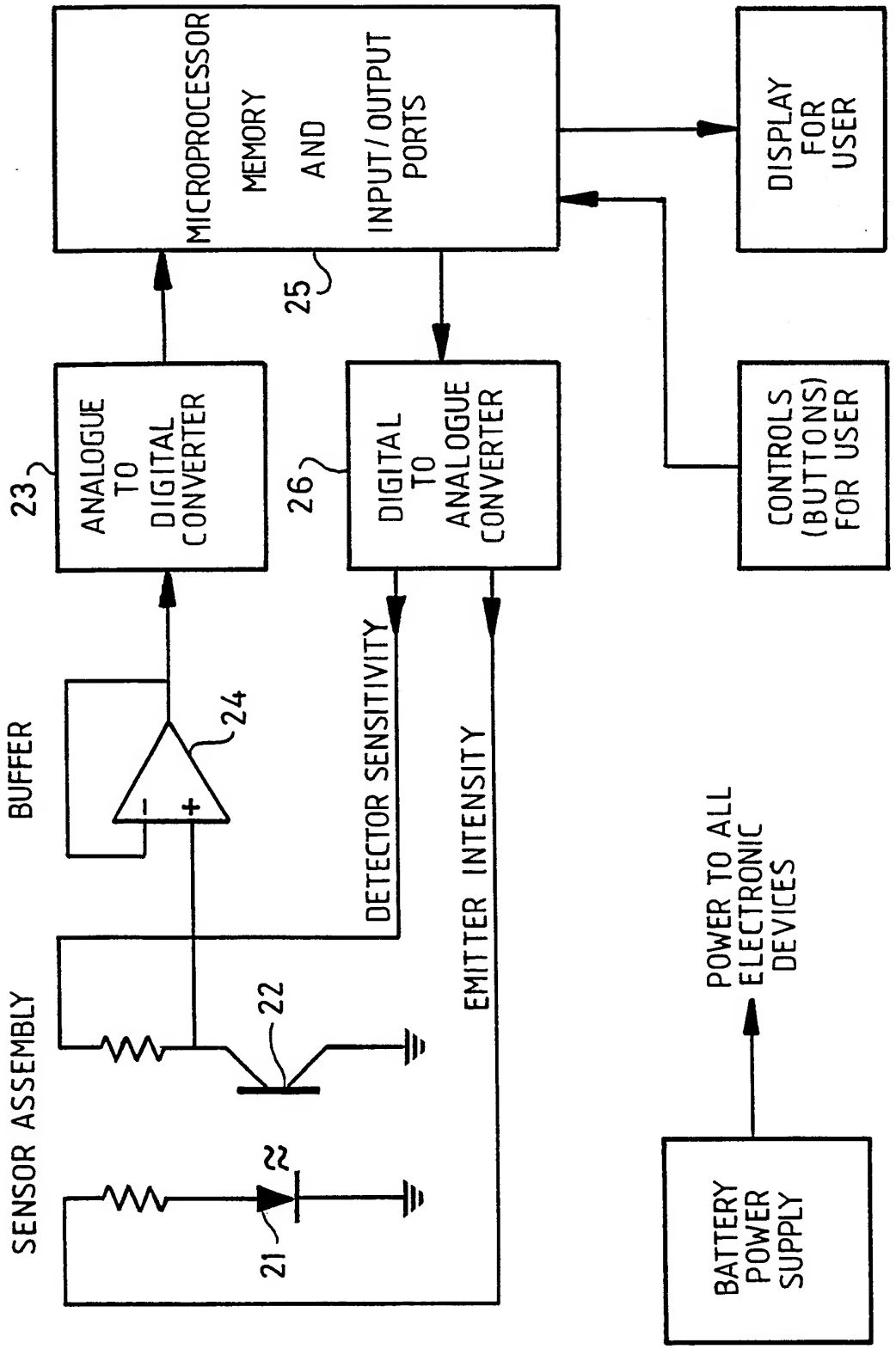
MICROPROCESSOR MEMORY AND INPUT/OUTPUT PORTS
25
DISPLAY FOR USER
ANALOGUE TO DIGITAL CONVERTER
23
DIGITAL TO ANALOGUE CONVERTER
26
CONTROLS (BUTTONS) FOR USER
BUFFER
24
DETECTOR SENSITIVITY
EMITTER INTENSITY
SENSOR ASSEMBLY
22
21
POWER TO ALL ELECTRONIC DEVICES
BATTERY POWER SUPPLY

Fig. 3

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/00302

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	US,A,4555179 (LANGERHOLE ET AL.) 26 November 1985 see figures 1-5, 8 see column 2, lines 39 - 63 see column 5, line 57 - column 8, line 17 see column 9, line 5 - column 10, line 21	1, 16
A		2, 5, 9, 10, 12-14, 17

X	US,A,4784150 (VOORHIES ET AL.) 15 November 1988 see figures 1-5, 11 see column 6, line 26 - column 8, line 57 see column 9, lines 21 - 68	1, 16
A		2, 3, 7-9, 12, 13, 17

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° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
08 JUNE 1990	19 JUIN 1990
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	CHEN A.H. A. Chen

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	EP,A,19478 (FIFE REGIONAL COUNCIL) 26 November 1980 see figures see page 1, line 32 - page 2, line 21 see page 3, line 1 - page 7, line 25	1, 16
A	---	2, 9, 17, 20
A	PHYSICS IN MEDICINE AND BIOLOGY. vol. 33, no. 6, June 1988, LONDON GB pages 711 - 722; FEATHER et al.: "A portable reflectometer for the rapid quantification of cutaneous haemoglobin and melanin." see abstract see page 714, line 6 - page 716, line 22; figures 3, 4	1-3, 6, 8, 9, 14, 16

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9000302

SA 34819

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/06/90
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4555179	26-11-85	None	
US-A-4784150	15-11-88	None	
EP-A-19478	26-11-80	None	